

Exhibit A

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 IN RE: ETHICON, INC., PELVIC :Master File No.
5 REPAIR SYSTEM PRODUCTS :2:12-MD-02327
6 LIABILITY LITIGATION :MDL No. 2327

7 -----
8 THIS DOCUMENT RELATES TO :JOSEPH R. GOODWIN
9 THE CASES LISTED BELOW :U.S. DISTRICT JUDGE
10 -----

11	Mullins, et al. v.	2:12-cv-02952
12	Ethicon, Inc., et al.	
13	Sprout, et al. v.	2:12-cv-07924
14	Ethicon, Inc., et al.	
15	Iquinto v. Ethicon,	2:12-cv-09765
16	Inc., et al.	
17	Daniel, et al. v.	2:13-cv-02565
18	Ethicon, Inc., et al.	
19	Dillon, et al. v.	2:13-cv-02919
20	Ethicon, Inc., et al.	
21	Webb, et al. v.	2:13-cv-04517
22	Ethicon, Inc., et al.	
23	Martinez v. Ethicon,	2:13-cv-04730
24	Inc., et al.	
25	McIntyre, et al. v.	2:13-cv-07283
	Ethicon, Inc., et al.	
	Oxley v. Ethicon,	2:13-cv-10150
	Inc., et al.	
	Atkins, et al. v.	2:13-cv-11022
	Ethicon, Inc., et al.	
	Garcia v. Ethicon,	2:13-cv-14355
	Inc., et al.	
	Lowe v. Ethicon,	2:13-cv-14718
	Inc., et al.	
	Dameron, et al. v.	2:13-cv-14799
	Ethicon, Inc., et al.	
	Vanbuskir, et al. v.	2:13-cv-16183
	Ethicon, Inc., et al.	

21
22 OCTOBER 5, 2015

23 MICHAEL P. WOODS, M.D.

24 GOLKOW TECHNOLOGIES, INC.

25 877.370.3377 ph|917.591.5672 fax

 deps@golkow.com

1	CAPTION CONTINUED:	
2	Mullens, et al. v.	2:13-cv-16564
	Ethicon, Inc., et al.	
3	Shears, et al. v.	2:13-cv-17012
	Ethicon, Inc., et al.	
4	Javins, et al. v.	2:13-cv-18479
	Ethicon, Inc., et al.	
5	Barr, et al. v.	2:13-cv-22606
	Ethicon, Inc., et al.	
6	Lambert v. Ethicon,	2:13-cv-24393
	Inc., et al.	
7	Cook v. Ethicon, Inc.,	2:13-cv-29260
	et al.	
8	Stevens v. Ethicon,	2:13-cv-29918
	Inc., et al.	
9	Harmon v. Ethicon, Inc.,	2:13-cv-31818
	et al.	
10	Snodgrass v. Ethicon,	2:13-cv-31881
	Inc., et al.	
11	Miller v. Ethicon, Inc.,	2:13-cv-32627
	et al.	
12	Matney, et al. v.	2:14-cv-09195
	Ethicon, Inc., et al.	
13	Jones, et al. v.	2:14-cv-09517
	Ethicon, Inc., et al.	
14	Humbert v. Ethicon,	2:14-cv-10640
	Inc., et al.	
15	Gillum, et al. v.	2:14-cv-12756
	Ethicon, Inc., et al.	
16	Whisner, et al. v.	2:14-cv-13023
	Ethicon, Inc., et al.	
17	Tomblin v. Ethicon,	2:14-cv-14664
	Inc., et al.	
18	Schepleng v. Ethicon,	2:14-cv-16061
	Inc., et al.	
19	Tyler, et al. v.	2:14-cv-19110
	Ethicon, Inc., et al.	
20	Kelly, et al. v.	2:14-cv-22079
	Ethicon, Inc., et al.	
21	Lundell v. Ethicon,	2:14-cv-24911
	Inc., et al.	
22	Cheshire, et al. v.	2:14-cv-24999
	Ethicon, Inc., et al.	
23	Burgoyne, et al. v.	2:14-cv-28620
	Ethicon, Inc., et al.	
24	Bennett, et al. v.	2:14-cv-29624
	Ethicon, Inc., et al.	
25		

1 BY MR. KUNTZ:

2 Q. You can -- and you're going to say that
3 over and over again, I know that, and Burt can ask
4 you those questions, but just answer my question for
5 now. Okay?

6 A. I'm aware of the internal documents.

7 Q. Okay. So the answer -- your answer is,
8 yes, Ethicon knew of all of the risks that you listed
9 out for me prior to the launch of the TVT?

10 MR. SNELL: Objection: Misstates,
11 totally misstates. He said he's aware of the
12 documents, but he did not consider that. You're
13 misstating his testimony.

14 BY MR. KUNTZ:

15 Q. Okay. So you did not consider the Ethicon
16 internal documents when forming your opinions that
17 you're here to talk about today?

18 A. Absolutely not.

19 Q. Okay. So you don't rely on any Ethicon
20 internal design documents in forming or giving your
21 opinions today?

22 A. I am looking at the evidence-based data
23 that's available.

24 Q. I think you just said, "Absolutely not."
25 Did you rely on any Ethicon design internal documents

1 obstructive symptoms.

2 Q. Okay. Why did you look at that mesh under
3 the microscope?

4 A. I just wanted to. I asked the pathologist
5 and I just wanted to look at it.

6 Q. You only wanted to do that one time with
7 explanted mesh?

8 A. I didn't feel a strong need to continue
9 looking. No, just the one time.

10 Q. Who was the pathologist?

11 A. I don't recall.

12 Q. When was this?

13 A. Several years. I couldn't give you a year
14 to be honest with you.

15 Q. You're not a biomaterials expert?

16 A. I -- I -- as I say, I've implanted, but I
17 would not consider -- call myself a biomaterials
18 expert.

19 Q. You're not an expert on warnings?

20 A. Actually, I have been consulted on -- I've
21 served on ACOG's Committee on Professional Liability;
22 I was vice chair of that committee. I've also served
23 on the ACOG's Quality and Patient Safety Committee
24 and I'm presently on AUGS' Quality Committee.

25 Q. Okay. What do those institutions -- what

1 do you do with warnings with those three groups?

2 A. Actually, looking on the safety design for,
3 say, obstetrical units and these kind of things.

4 Q. Okay. What do you mean safety design? For
5 the actual unit at the hospital?

6 A. Yes.

7 Q. Okay. So you work with warnings for, like,
8 beds in hallways?

9 A. Well, what I do is looking at hospital
10 design or team design for patient safety, is a better
11 way to describe it.

12 Q. You're not an expert on warnings related to
13 medical devices, correct?

14 A. No, I would not call myself an expert.

15 Q. Okay. I mean, you don't know what risk
16 information a medical device company needs to put
17 inside an IFU, do you?

18 MR. SNELL: Objection, form.

19 THE WITNESS: I believe that the FDA
20 has very specific guidelines.

21 BY MR. KUNTZ:

22 Q. Okay. You don't know what those are as we
23 sit here today?

24 A. No, I do not.

25 Q. Okay. You've never looked at them, have

1 study, and it was either late 1990s or early 2000s.

2 Q. Okay. So you ran a study for them after
3 the product was designed?

4 A. No. I had done using another device that
5 was shorter on a vaginal hysterectomy randomized
6 study.

7 Q. Do you know what a company research is
8 before a product is designed or released?

9 MR. SNELL: Form, vague, overbroad,
10 incomplete hypothetical.

11 BY MR. KUNTZ:

12 Q. You can answer.

13 A. I have vague ideas, but I -- I have no
14 solid regulatory aspect at all.

15 Q. Okay.

16 A. I'm usually asked, you know, such as with
17 my work with Ethicon is, "What is your opinion on
18 this?" I worked on a couple of the other -- the
19 other, like with TVT Secur, and then looking at some
20 of the evolution ones, but as in the regulation, that
21 is something that's not what I would -- I've got
22 other things to be worried about.

23 Q. You wouldn't consider yourself an expert in
24 that area?

25 A. Pardon me?

1 Q. You're not an expert in that area, correct?

2 MR. SNELL: Form, "that area."

3 THE WITNESS: I feel that I do not
4 have the knowledge base. I may have a very vague
5 knowledge base but not the level that would be
6 required in manufacturing.

7 BY MR. KUNTZ:

8 Q. Tell me how a medical device company goes
9 about designing a medical device.

10 MR. SNELL: Objection: Form,
11 overbroad.

12 THE WITNESS: I feel that in the
13 device they get an idea, and they do benchtop work,
14 and then it evolves through; and I would say I'm more
15 at the end of that process.

16 BY MR. KUNTZ:

17 Q. Okay. What experts are involved?

18 A. It would depend on what type of device.

19 Q. What about an SUI device?

20 A. I believe that with that you would have to
21 have your mechanical engineers, you would have to
22 have your safety individuals, you would have to have
23 consulting with medical personnel, "Is this even a
24 real option to be looking at?"

25 Q. What's a design history file?

1 A. I -- again, I -- I would suspect, by that
2 name, that it is the life -- the evolution of a
3 device.

4 Q. Okay. Did you review the design history
5 file for the TVT Retropubic?

6 A. I reviewed over -- I don't recall
7 specifically on that. When Ulmsten was first coming
8 out with this, with the integral theory, I found it
9 to be a real challenge to my dogma, for one, but in
10 looking at how he talked about using the various
11 suburethral components, I did look at that.

12 Q. Okay. Do you know, one way or another, if
13 you reviewed the design history file for the TVT, as
14 we sit here right now?

15 A. I did not. I do not have a bundle that
16 says that's what it is, no.

17 Q. Okay. Do you know what MedScan is?

18 A. I've heard of it. I'm not exactly -- I
19 believe that is -- I will say it would be pure
20 conjecture on --

21 Q. Do you know what Preventia is? Have you
22 ever heard of Preventia?

23 A. No. Actually, I might have heard -- the
24 name sounds, but...

25 Q. What's a failure modes and effects

1 analysis?

2 A. I'm not sure.

3 Q. So safe to -- it's accurate to say you're
4 not sure what the purpose of a failure modes and
5 effects analysis is because you don't know what it
6 is?

7 A. Correct.

8 Q. Do you know -- do you recall, as you sit
9 here now, if you reviewed any of the failure modes
10 and effects analysis involved in this case?

11 A. If I did, it would have been very briefly.

12 Q. Do you know if warnings for a product are
13 part of the failure modes analysis?

14 A. If I don't know exactly what the failure
15 modes analysis is, I can't say that.

16 Q. Do you know what a DDSA is?

17 A. That name rings a bell. I'm trying --

18 Q. So you don't know, as we sit here right
19 now, or you don't recall?

20 A. Don't -- do not recall.

21 Q. What is ISO testing?

22 A. ISO testing is a standardized testing that
23 is used -- it's International Standards -- I want to
24 say Organization. I remember this some from my ICON
25 days.